How to treat patients after natalizumab discontinuation: the TY-STOP 2 study, an Italian, prospective and multicenter study

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Background: Natalizumab (NTZ) is notoriously associated with progressive multifocal leukoencephalopathy (PML) with a global incidence of 4.20 per 1000 treated patients. After 24 courses, patients and physicians decide whether to continue NTZ or not: a previous study (TY-STOP) showed a stopping rate of about 65%.
Goals: To describe study design, methods, state of enrollment, and preliminary results of the TY-STOP2 study, aimed to compare the efficacy and safety continuing versus not continuing NTZ.
Methods: An Italian, multicenter (8 centres), prospective, observational study, enrolling patients after at least 24 NTZ administrations. Patients underwent clinical evaluation, magnetic resonance imaging (MRI) and John Cunningham virus (JCV) antibodies testing every three months.
Results: Recruitment is still ongoing. Up to now 138 patients have been enrolled: mean age at baseline 37.3 years (SD: 10.7); median expanded disability status scale (EDSS) 2.0 (range: 0-6.5); mean disease duration 8.9 years; ARR pre-NTZ: 0.94. 125 patients (90.6%) continued NTZ after 24 courses; 8/13 that discontinued were JCV-positive (on total of positive of 59/138). During the follow-up, 3 patients stopped NTZ after 6 months, 4 after 9 and 2 after 12. A total of 6 patients out of 126 (4.8%) had a clinical relapse in the first year after 24 courses. Of these, only 1 had stopped NTZ. 8/87(9.2%) patients with available data had an EDSS increase >= 1 point in the first 12 months (delta EDSS: median 0 (range: -2.5 - 2)) and 1 of these have discontinued NTZ. 5/103 patients (4.9%) showed at least an active MRI during the first 12 months of follow-up and 1/9 of these with available information had stopped NTZ. 11/74 (14.9%) had an adverse event in the first 12 months (1 serious).
Conclusion: This descriptive analysis shows a NTZ stopping rate lower (10%) than in TY-STOP (65%), this is probably due to a better known PML management. However, PML is still a serious NTZ adverse event and more alternative drugs are and will become available. This will probably lead to a higher number of switching patients in our, still ongoing, recruitment. Our study will try to identify a possible therapeutic strategy preserving disease stability and preventing the occurrence of PML.
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